INDEX TO VOLUME 76

POSTGRADUATE MEDICINE

JULY-DECEMBER 1984

SUBJECTS

ABDOMEN
• Evaluation with nuclear magnetic resonance imaging. 76(6):166
ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)
• Causes, therapy. 76(1):167*
ADOLESCENT MEDICINE: See Pediatrics
ADRENAL GLANDS
• Age-related changes, steroid medication. 76(1):65*
AGING
• Changes in face, nonsurgical and surgical treatment, prevention. 76(7):37*
• Hypertension, drug therapy, special management considerations. 76(5):46*
• Hypertension, hygienic management measures. 76(5):61*
• Macular degeneration, laser photocoagulation therapy. 76(7):54
• Medications, hazards of overuse. 76(1):50*
• Presbycusis, evaluation for appropriate treatment. 76(3):189*
• Steroid medication, adverse effects. 76(1):65*
AIDS: See Acquired immune deficiency syndrome
AIRWAY OBSTRUCTION
• Diagnosis by bronchial provocation testing, guidelines for safe use. 76(5):161
• Inhalation agents and devices. 76(5):194*
• Management. 76(1):209*
• Occupational, causes and management. 76(5):179*
• Role of arachidonic acid metabolites. 76(5):140
ALLERGY
• Atopic dermatitis, recognition, treatment. 76(1):139*
• Atopic diseases, characteristics. 76(1):118*
• Fire ant, diagnosis, treatment. 76(1):155*
• Food, possible cause of eczema, effect of dietary manipulation. 76(8):51
• Food, review of food extract injection therapy. 76(2):59
• In urticaria and angioedema, diagnosis, treatment. 76(1):184*
• Rhinitis and conjunctivitis, diagnosis, treatment. 76(1):197*

*Major clinical discussion
CR, Case Report
ED, Editorial
OP, Opinion
PH, Physician-at-Large
VP, Viewpoint

AMERICAN COLLEGE OF CARDIOLOGY
• Report on Annual Session. 76(2):231
ANGINA PECTORIS: See Cardiovascular diseases
ANTIBIOTICS: See Drugs, antibiotics
ARTHRITIS: See Rheumatic diseases
ASTHMA
• Diagnosis by bronchial provocation testing, guidelines for safe use. 76(5):161*
• Inhalation agents and devices. 76(5):194*
• Management. 76(1):209*
• Occupational, causes and management. 76(5):179*
• Role of arachidonic acid metabolites. 76(5):140*
ATOPY
• Definition, characteristics of atopic diseases. 76(1):118*

BEHAVIOR THERAPY
• In treatment of hypertension. 76(5):66*
BITES AND STINGS
• Fire ant allergy, diagnosis, treatment. 76(1):155*
BLEEDING: See Hemorrhage
BLOOD COAGULATION
• Abnormalities, in nephrotic syndrome. 76(6):111
• Disorders, evaluation and management. 76(8):118*
• Disorders, laboratory diagnosis, basic screening tests. 76(8):137
BLOOD GLUCOSE
• Hypoglycemia, reactive, diet-induced, possible positive effect of dietary manipulation. 76(8):52
BONE DISEASES
• Osteomyelitis, hematogenous, diagnosis and treatment. 76(4):79*
• Tumors in children, diagnostic evaluation. 76(4):87*
BREAST DISEASES
• Cancer, management by surgery or adjuvant chemotherapy. 76(7):155**

CANCER: See Neoplasms
CARDIOVASCULAR DISEASES
• Action of beta-adrenergic blocking agents. 76(3):71*
• Angina pectoris, diagnosis. 76(3):50*
• Cardiac arrest, improving survival rates through community resuscitation program. 76(3):85*
• Circulation, assessment to adjust hypertension treatment regimen. 76(7):115
• Circulation, blood coagulation disorders, evaluation and management. 76(8):118*
• Congestive heart failure, drug therapy. 76(2):187*
• Heart, evaluation with nuclear magnetic resonance imaging. 76(6):165
• Hyperlipidemia, evaluation and treatment. 76(6):49*
• Hypertension, circulatory assessment to adjust therapeutic regimen. 76(7):115*
• Hypertension, drug therapy, mechanism of action, side effects. 76(7):84*
• Hypertension, economics of antihypertensive therapy. 76(7):97*
• Hypertension, elderly, drug therapy, special considerations. 76(5):46*
• Hypertension, elderly, hygienic measures. 76(5):61*
• Hypertension, mild, how to treat. 76(7):107*
• Hypertension, renovascular, use of balloon catheter angioplasty. 76(7):131*
• Hypertension with hypokalemia, caused by aldosterone-secreting adrenal adenoma. (CR) 76(2):173
• Prevention with magnesium supplementation. 76(8):61
• Prevention with marine lipid (fish oil) intake. 76(8):62
• Report on Annual Session of American College of Cardiology. 76(2):231
• Risk factors, identification and minimization. 76(6):52
• Thromboembolic complications in nephrotic syndrome. 76(6):111*
• Thrombotic disorders, anticoagulant treatment. 76(8):151*
• Vasculitides, respiratory manifestations. 76(3):124
• Venous insufficiency, cause of leg ulcers, treatment. 76(4):51*
CATHETERIZATION
• Balloon dilation of stenotic renal artery in renovascular hypertension. 76(7):131*
CHEMOTHERAPY: See Drugs, antineoplastic
CIRCULATION: See Cardiovascular diseases
CLINICS, MEDICAL
• Mason, philosophy, history. (ED) 76(7):11
• Mayo, philosophy, history. (ED) 76(3):13
COLONIC DISEASES: See Gastrointestinal diseases
COMPUTERS, MEDICAL
• Image processing in health care. 76(2):73
• Microcomputers in medical practice. 76(1):239
• Security techniques. 76(6):171
• Security techniques for physician's office. 76(8):187
CORTICOSTEROIDS: See Drugs, corticosteroids
COST-BENEFIT ANALYSIS
• Antihypertensive therapy, unit costs. 76(7):97
• Automated office laboratory equipment, purchase considerations. 76(5):211
• Diagnostic tests for coronary artery disease. 76(3):50
CROWD EVENTS
• Medical care, planning guidelines. 76(2):44*

DRG: See Diagnosis-related group
DELIVERY OF HEALTH CARE
• Concerns about new DRG reimbursement program. (ED) 76(1):13
• Emergency dental services in Norway, observations. (PH) 76(6):22
• Mason Clinic, philosophy, history. (ED) 76(7):11
• Mayo Clinic, philosophy, history. (ED) 76(3):13
• Personalized care, or should physicians practice "generic medicine"? (PH) 76(8):22
DERMATITIS
• Atopic, recognition and treatment. 76(1):139*
• Eczema, possibly caused by food allergy, effect of dietary manipulation. 76(8):51
DIABETES
• Insulin-dependent, role of continuous subcutaneous insulin infusion. 76(8):80*
• Urine glucose tests in management, study of double-void technique. (VP) 76(3):204
DIAGNOSIS-RELATED GROUP (DRG)
• Concerns. (ED) 76(1):13
DIAGNOSTIC TECHNIQUES
• Arthroscopy, in acute knee injury. 76(8):43
• Aspiration and Craig needle biopsy, for osteomyelitis. 76(4):82
• Bronchial provocation testing, guidelines for safe use. 76(5):161
• Endoscopy, upper gastrointestinal, in Mallory-Weiss syndrome. 76(8):190, 191, 192
• Invasive, for angina pectoris. 76(3):62
• Noninvasive, for angina pectoris. 76(3):50
• Nuclear magnetic resonance imaging, clinical applications. 76(6):159*
DIET: See Nutrition
DOUCHING
• Vaginal, pros, cons, and proper technique. (VP) 76(8):93

continued on page 228

Brief Summary

Indications: Relief of mild to moderate pain; treatment of primary dysmenorrhea.

Contraindications: Contraindicated in patients who have had allergic reactions to NAPROSYN or ANAPROX. Do not give to patients in whom aspirin or other nonsteroidal anti-inflammatory/analgesic drugs induce the syndrome of asthma, rhinitis, and nasal polyps.

Warnings: Gastrointestinal bleeding, sometimes severe, and occasionally fatal, has been reported in patients receiving the drug. Among 960 patients treated for rheumatoid arthritis or osteoarthritis, 16 cases of peptic ulceration were reported. More than half were on concomitant corticosteroid and/or salicylate therapy and about a third had prior history of peptic ulcer. Gastrointestinal bleeding including nine potentially serious cases, was also reported. These were not always preceded by premonitory gastrointestinal symptoms. Although most of the patients with serious bleeding were receiving concomitant therapy and had a history of peptic ulcer disease, the drug has the potential for causing gastrointestinal bleeding on its own. Do not give to patients with active peptic ulcer unless potential benefit outweighs risk. Administer to such patients and others with history of gastrointestinal disease only under close supervision.

Precautions: General: NAPROSYN® (NAPROXEN) SHOULD NOT BE USED CONCOMITANTLY WITH THE RELATED DRUG ANAPROX® (NAPROXEN SODIUM) SINCE THEY BOTH CIRCULATE IN PLASMA AS THE NAPROXEN ANION. Because anaphylactic reactions usually occur in patients with a history of such reactions, question patients for such things as asthma, nasal polyps, urticaria, and hypotension associated with NSAIs before starting therapy. If such symptoms occur, discontinue the drug. In chronic studies in laboratory animals, the drug has caused nephritis. Glomerular nephritis, interstitial nephritis and nephrotic syndrome have been reported. Use with great caution in patients with significantly impaired renal function. Monitoring of serum creatinine and/or creatinine clearance is advised in these patients. Use caution if drug is given to patients with creatinine clearance less than 20 ml/minute. Certain patients, including those with compromised renal blood flow and some elderly in whom impaired renal function may be expected, should have renal function assessed before and during therapy. Consider reducing daily dosage in these patients. Use caution when high doses are required in elderly patients or in patients with chronic alcoholic liver disease or cirrhosis. With NSAIs borderline elevations of liver tests may occur in up to 15% of patients. They may progress, remain unchanged, or be transient with continued therapy. The SGPT (ALT) test is probably the most sensitive indicator of liver dysfunction. Elevations (3 times the upper limit of normal) of SGPT or SGOT (AST) occurred in controlled clinical trials in less than 1% of patients. Evaluate patients with symptoms and/or signs suggesting liver dysfunction, or in whom an abnormal liver test has occurred, for evidence of more severe hepatic reaction. Severe hepatic reactions, including jaundice and cases of fatal hepatitis, have been reported rarely. If abnormal liver tests persist or worsen, if clinical signs and symptoms consistent with liver disease develop, or if systemic manifestations occur (e.g., eosinophilia or rash), discontinue therapy. If steroid dosage is reduced or eliminated during therapy, do so slowly and observe patients closely for adverse effects, including adrenal insufficiency and exacerbation of arthritis symptoms. Determine hemoglobin values frequently for patients with initial values of 10 grams or less who receive long-term therapy. Peripheral edema has been observed in some patients. Each tablet contains approximately 25 mg (1 mEq) sodium, which should be considered in patients whose overall intake of sodium must be markedly restricted. Use with caution in patients with fluid retention, hypertension or heart failure. The antipyretic and anti-inflammatory activities of the drug may reduce fever and inflammation, thus diminishing their utility as diagnostic signs. Conduct ophthalmic studies soon after starting therapy and at periodic intervals if the drug is used for an extended period.

Information for Patients: Caution should be exercised by patients whose activities require alertness if they experience drowsiness, dizziness, vertigo or depression during therapy.

Drug Interactions: Naproxen anion may displace other albumin-bound drugs from their binding sites and could likewise be displaced itself. Studies failed to show that the drug significantly affects prothrombin times when administered to individuals on coumarin-type anticoagulants; but use caution since interactions have been shown with other nonsteroidal agents of this class. Observe patients receiving the drug and a hydantoin, sulfonamide or sulfonylurea for signs of toxicity to these drugs. Some drugs of this class inhibit the natriuretic effect of furosemide. Increased plasma lithium due to inhibition of renal lithium clearance has been reported. This drug and other NSAIs can reduce the antihypertensive effect of beta-blockers. Probenecid given concurrently increases naproxen anion plasma levels and extends its plasma half-life significantly. Use caution if given concurrently with methotrexate.

Drug/Laboratory Test Interactions: The drug may decrease platelet aggregation and prolong bleeding time. The drug may result in increased urinary values for 17-ketogenic steroids because of an interaction between the drug and/or its metabolites with m-dinitrobenzene used in this assay. Temporarily discontinue therapy with the drug for 72 hours before adrenal function tests are performed. The drug may interfere with some urinary assays of 5-hydroxy indoleacetic acid (5HIAA).

Carcinogenesis: A two-year study in rats to evaluate the carcinogenic potential of the drug showed no evidence of carcinogenicity.

Pregnancy: Teratogenic Effects: Pregnancy Category B. Do not use during pregnancy unless clearly needed. Avoid use during late pregnancy. Non-teratogenic Effects: In rats, pregnancy was prolonged when the drug was given before the onset of labor; labor was protracted when the drug was given after labor had begun.

Nursing Mothers: Avoid use in nursing mothers.

Pediatric Use: Pediatric indications and dosage recommendations have not been established.

Adverse Reactions: Incidence Greater than 1%: Gastrointestinal: The most frequent complaints related to the gastrointestinal tract: Constipation,* heartburn,* abdominal pain,* nausea,* dyspepsia, diarrhea, stomatitis. **Central Nervous System:** Headache,* dizziness,* drowsiness,* lightheadedness, vertigo. **Dermatologic:** Itching (pruritus),* skin eruptions,* ecchymoses,* sweating, purpura. **Special Senses:** Tinnitus,* hearing disturbances, visual disturbances. **Cardiovascular:** Edema,* dyspnea,* palpitations. **General:** Thirst.
*Incidence of reported reaction 3%-9%. Reactions seen in less than 3% of the patients are unmarked.

Incidence Less Than 1%: Probable Causal Relationship: Gastrointestinal: Abnormal liver function tests, gastrointestinal bleeding, hematemesis, jaundice, melena, peptic ulceration with bleeding and/or perforation, vomiting. **Renal:** Glomerular nephritis, hematuria, interstitial nephritis, nephrotic syndrome, renal disease. **Hematologic:** Eosinophilia, granulocytopenia, leukopenia, thrombocytopenia. **Central Nervous System:** Depression, dream abnormalities, inability to concentrate, insomnia, malaise, myalgia and muscle weakness. **Dermatologic:** Alopecia, skin rashes. **Special Senses:** Hearing impairment. **Cardiovascular:** Congestive heart failure. **General:** Anaphylactoid reactions, menstrual disorders, pyrexia (chills and fever). **Causal Relationship Unknown: Hematologic:** Agranulocytosis, aplastic anemia, hemolytic anemia. **Central Nervous System:** Cognitive dysfunction. **Dermatologic:** Urticaria. **General:** Angioneurotic edema, hyperglycemia, hypoglycemia. **Overdosage:** May be characterized by drowsiness, heartburn, indigestion, nausea or vomiting. Life-threatening dose is not known. If patient ingests many tablets, empty stomach and employ usual supportive measures. Animal studies suggest that the prompt administration of 5 grams of activated charcoal would tend to reduce markedly drug absorption. It is not known if the drug is dialyzable.

Dosage and Administration for Mild to Moderate Pain, Dysmenorrhea and Acute Tendinitis and Bursitis: The recommended starting dose is two 275 mg tablets, followed by one 275 mg tablet every 6 to 8 hours, as required. The total daily dose should not exceed 5 tablets (1375 mg).

Caution: Federal law prohibits dispensing without prescription.
See package insert for full Prescribing Information.

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SYNTEX

SYNTEX PUERTO RICO, INC
HUMACAO, PUERTO RICO 00661

INDEX TO VOLUME 76
CONTINUED FROM PAGE 225

DRUG ADMINISTRATION
- New methods to narrow fluctuations in plasma levels. 76(5):71
- Transcutaneous, advantages and disadvantages. 76(5):77, 78

DRUG INTERACTIONS
- In elderly. 76(1):52

DRUG THERAPY
- Aerosol, for asthma and bronchitis. 76(5):194
- For asthma. 76(1):217
- For chronic pain relief. (VP) 76(2):215
- For congestive heart failure, overview. 76(2):187*
- For hypertension, in elderly, special considerations. 76(5):46*
- For hypertension, seven drug classes, mechanism of action, side effects. 76(7):84*
- For hypertension, unit costs. 76(7):97
- For mild hypertension, when to use. 76(7):107*
- In elderly, hazards of overmedication. 76(1):50*

DRUGS, ANTIARRHYTHMIC
- Beta-adrenergic blockers for cardiovascular disease. 76(3):71

DRUGS, ANTIBIOTICS
- For hematogenous osteomyelitis. 76(4):82
- For mycoplasmal pneumonia. (CR) 76(6):78
- Reduction in use to control bacterial resistance. 76(6):63*

DRUGS, ANTIHYPERLIPIDEMIC
- For lowering lipid levels to minimize coronary risk factors. 76(6):54

DRUGS, ANTIHYPERTENSIVE
- For mild hypertension, when to use. 76(7):107*
- Seven classes, mechanism of action, side effects. 76(7):84*
- Unit costs. 76(7):97

DRUGS, ANTINEOPLASTIC
- For breast cancer, effects on survival rates. 76(7):157, 160
- For polycythemia vera. (VP) 76(5):104

DRUGS, CALCIUM CHANNEL BLOCKERS
- For asthma. 76(5):151

DRUGS, CORTICOSTEROIDS
- For asthma. 76(5):151
- For nephrotic syndrome. 76(6):93
- Glucocorticoids, for sarcoidosis. 76(3):171
- In elderly, adverse effects. 76(1):65*
- Topical, for atopic eczema. 76(1):141

DRUGS, DIURETICS
- Complications in nephrotic patients. 76(6):138
- For edema in nephrotic patients. 76(6):138

DRUGS, DOSAGE FORMS
- Zero-order drug delivery, maintaining appropriate plasma concentrations. 76(5):71

DRUGS, HYPNOTICS
- For insomnia. 76(1):86

DRUGS, MIOTICS
- Ocular insert for pressure reduction in glaucoma. 76(5):72

DRUGS, NARCOTICS
- For chronic pain relief. (VP) 76(2):215

DRUGS, PLATELET INHIBITORS
- For thrombotic disorders, clinical uses. 76(8):160

DRUGS, SIDE EFFECTS
- From beta-adrenergic blocking agents. 76(3):76
- Granulocytopenia. 76(8):175
- In antihypertensive treatment. 76(7):116
- Steroid medication in elderly. 76(1):65

DRUGS, SUSTAINED RELEASE
- Mechanisms, indications. 76(5):72

DRUGS, THROMBOLYTIC ENZYMES
- For thrombi dissolution, pharmacology, dosing, adverse effects, and clinical uses. 76(8):161

DRUGS, TOCOLYTIC
- Use in pregnant women with proteinuria. 76(6):128

EDEMA
- In nephrotic syndrome, pathogenesis and management. 76(6):135*

EDUCATION, MEDICAL
- Preparation for public office. (ED) 76(5):13

ELECTROLYTES
- Abnormalities, occurrences in nephrotic syndrome. 76(6):142

EMERGENCY MEDICINE
- Cardiac arrest, improving survival rates through community resuscitation program. 76(3):85*
- For mass gatherings, planning guidelines. 76(2):44*

ENDOCRINE DISORDERS
- Adrenal adenoma, aldosterone-secreting, cause of hypertension. (CR) 76(2):173
- Adrenal function, age-related changes, steroid medication guidelines. 76(1):65*
- Diabetic: See Diabetes
- Respiratory involvement. 76(3):131

ENDOSCOPY
- Upper gastrointestinal, in Mallory-Weiss syndrome. 76(8):190, 191, 192

EQUIPMENT
- Cochlear prosthesis, to enhance communication skills of the deaf. 76(7):73*
- Tonometer, Schiotz, for glaucoma screening. (VP) 76(1):224

ETHICS, MEDICAL
- Physicians skipping out on disciplinary action. (ED) 76(2):13

EXERCISE
- Heat stress in young athletes, treatment and prevention. 76(1):109*
- In treatment of hypertension. 76(5):66

EYE DISORDERS
- Allergic conjunctivitis, diagnosis, treatment. 76(1):197
- Glaucoma, laser therapy. 76(7):53
- Glaucoma, screening. (VP) 76(1):224
- Laser photocoagulation therapy. 76(7):51*
- Macular degeneration, aging-related, laser therapy. 76(7):54
- Ocular causes of face pain. 76(2):149*

• Retinopathy, diabetic, laser therapy. 76(7):52

FACE
• Aging, nonsurgical and surgical treatments, prevention. 76(7):37*
• Pain, importance of ears, nose, and throat in evaluation. 76(2):133*
• Pain, neurologic causes. 76(2):161*
• Pain, ocular causes. 76(2):149*
• Pain, overview. 76(2):90*
• Pain, role of trigeminal nerve. 76(2):101*
• Pain, temporomandibular joint disorders, dental evaluation. 76(2):121*

FACIAL PARALYSIS
• Non-Bell's palsies, evaluation, management. 76(1):95*

FETAL MONITORING
• In high-risk pregnancy. 76(4):37

FLUID RETENTION
• In nephrotic syndrome, pathogenesis and management. 76(6):135*

GAIT
• In children, problems, recognition and management. 76(4):56*

GASTROINTESTINAL DISEASES
• Enteric infection, gay bowel syndrome, diagnosis and treatment. 76(2):197*
• Esophageal reflux, surgical treatment. 76(7):77*
• Mallory-Weiss syndrome, diagnosis and management. 76(8):189*
• Respiratory involvement. 76(3):137

GENETIC DISORDERS: See Hereditary diseases

GERIATRICS: See Aging

GLAUCOMA
• Laser photocoagulation therapy. 76(7):53
• Screening for prevention. (VP) 76(1):224

GYNECOLOGY: See Obstetrics/Gynecology

HANDICAPPED
• Mentally, deinstitutionalization, compassionate move or great mistake? (ED) 76(6):13

HEADACHE
• Facial migraine, evaluation. 76(2):133

HEALTH PROMOTION
• Role of physician in helping patients prevent illnesses. (OP) 76(5):223

HEARING DISORDERS
• Deafness, cochlear prosthesis for enhancement of communication skills. 76(7):73*
• Presbycusis, evaluation for appropriate treatment. 76(3):189*

HEART DISEASE: See Cardiovascular diseases

HEMATOLOGIC DISEASES: See also Hemorrhage
• Coagulation abnormalities in nephrotic syndrome. 76(6):111
• Erythrocytosis, evaluation and therapy. (VP) 76(5):98
• Granulocytopenia, characteristics, causes, evaluation, and management. 76(8):175*
• Hyperlipidemia, evaluation and treatment. 76(6):49*
• Laboratory diagnosis, basic screening tests. 76(8):137*
• Nephrotic syndrome and pregnancy, evaluation. 76(6):125
• Nephrotic syndrome, diagnosis and therapy. 76(6):88*
• Nephrotic syndrome in neoplastic illness, incidence and clinical presentations, implications. 76(6):147*
• Proteinuria, effect on pregnancy. 76(6):127
• Respiratory manifestations. 76(3):129
• Sickle cell disease, zinc supplementation to stimulate growth. 76(5):249
• Thrombocytopenia, characteristics, causes, evaluation, and management. 76(8):171*
• Thrombotic disorders, anticoagulant treatment. 76(8):151*

HEMORRHAGE
• Adverse effect of anticoagulants. 76(8):156, 159, 162
• Bleeding disorders, laboratory diagnosis, basic screening tests. 76(8):137*
• Presenting symptom of thrombocytopenia. 76(8):171
• Spontaneous, indicative of coagulation factor abnormalities, evaluation and management. 76(8):118
• Upper gastrointestinal, Mallory-Weiss syndrome, diagnosis and management. 76(8):189*

HEMORRHAGIC DISORDERS: See Hemorrhage

HEPARIN
• Prophylaxis for thrombosis, pharmacology, dosing, adverse effects, and clinical uses. 76(8):153

HEREDITARY DISEASES
• Coagulation factor abnormalities, evaluation and management. 76(8):118*
• Congenital neutropenia. 76(8):178

HOSPITALS, COMMUNITY
• Experience with Mallory-Weiss syndrome. 76(8):189*
• Granting privileges, evaluating physician credentials. (ED) 76(4):9

HYPERBARIC OXYGEN TREATMENT
• Indications for use, risks. 76(5):83*

HYPERTENSION: See Cardiovascular diseases

IMMUNIZATION
• Recommendations for travel. 76(5):243

IMMUNOLOGIC DISEASES
• Acquired immune deficiency syndrome, causes, therapy. 76(1):167*
• Allergic rhinitis and conjunctivitis, diagnosis, treatment. 76(1):197*
• Atopic dermatitis, recognition, treatment. 76(1):139*
• Atopic diseases, characteristics. 76(1):118*
• Fire ant allergy, diagnosis, treatment. 76(1):155*
• Urticaria and angioedema, diagnosis, treatment. 76(1):183*

IMMUNOTHERAPY
• For asthma. 76(1):212
• For fire ant stings. 76(1):160

INFECTION
• Bacterial, nasal involvement. 76(3):102
• Cause of neutropenia. 76(8):179
• Enteric, in homosexual men, diagnosis and treatment. 76(2):197*
• Fungal, nasal involvement. 76(3):103
• Hematogenous osteomyelitis, diagnosis and treatment. 76(4):79*
• Mycoplasmal pneumonia, diagnosis and treatment. (CR) 76(6):71
• Neck, localized, signs, complications, and treatment. 76(8):69, 72
• Neck, nonlocalized, necrotic and nonnecrotic, signs, complications, and treatment. 76(8):69, 75
• Opportunistic, in acquired immune deficiency syndrome. 76(1):170, 173, 174
• Resistant to antibiotic treatment. 76(6):63*
• Sepsis outside biliary tract, cause of abnormal liver test results. 76(7):63
• Sexually transmitted, in homosexual men, diagnosis and treatment. 76(2):197*
• Vulvovaginitis in adolescent girls, cause of dysuria, diagnosis and treatment. 76(8):207

INFLAMMATION
• Leg ulcer, recognizing underlying disorder. 76(4):51

INSECT BITES AND STINGS
• Fire ant allergy, diagnosis, treatment. 76(1):155*

INSOMNIA
• Hypnotic treatment. 76(1):83*

INSULIN
• Continuous subcutaneous infusion, principles of use. 76(8):80*
• Infusion pumps, advantages and disadvantages. 76(5):78

INTESTINAL DISEASES: See Gastrointestinal diseases

KIDNEY DISEASES
• Nephrotic syndrome, diagnosis and therapy. 76(6):88*
• Nephrotic syndrome, effects on pregnancy. 76(6):125*
• Nephrotic syndrome, fluid and electrolyte abnormalities. 76(6):135*
• Nephrotic syndrome in neoplastic illness, incidence and clinical presentation, implications. 76(6):147*
• Nephrotic syndrome, thromboembolic complications. 76(6):111*
• Respiratory involvement. 76(3):133

KNEE INJURIES
• Acute, assessing ligament stability, treatment and prevention. 76(8):38*

LABORATORY EQUIPMENT
• Automated, physician's office, purchase considerations. 76(5):211

LABORATORY INVESTIGATION
• Bleeding disorders, basic diagnostic tests. 76(8):137*
• For ectopic pregnancy. 76(2):66
• For rheumatologic diseases. 76(3):155*
• In evaluating cause of dysuria in adolescent girls. 76(8):214
• In nephrotic syndrome. 76(6):91
• Pap smear screening, frequency and interpretation. 76(6):36

LARYNGEAL DISEASES
• Recognition, treatment. 76(4):26, 30, 32, 34

LASERS
• For eye disorders. 76(7):51*

LIVER DISEASES
• Abnormal liver test results caused by disorders outside the hepatobiliary system. 76(7):62*

LYMPHATIC DISEASES
• Sarcoidosis, diagnosis and treatment. 76(3):167*

MEDICAL PRACTICE
• Automated office laboratory equipment, purchase considerations. 76(5):211
• Clinical impressions versus scientific evidence, effects of unwarranted generalizations. (ED) 76(8):13
• Computer security methods for physician's office. 76(8):187
• Concerns about new DRG reimbursement program. (ED) 76(1):13
• Criticisms in press from physician colleagues, issue of free speech. (PH) 76(5):22
• Group, Mason Clinic. (ED) 76(7):11
• Group, Mayo Clinic. (ED) 76(3):13
• Hospital privileges, evaluating physician credentials. (ED) 76(4):9
• Medical records, importance of effective and timely completion. (OP) 76(8):219
• Patient behavior during office visits, anticipating their additional problems. (PH) 76(7):18
• Physicians skipping out on disciplinary action. (ED) 76(2):13
• Use of microcomputers. 76(1):239

MEDICAL RECORDS
• Importance of effective and timely completion. (OP) 76(8):219

MIGRAINE: See Headache

MUSCULOSKELETAL DISORDERS
• Gait problems in children, recognition and management. 76(4):56*
• Hip problems in children, early recognition. 76(4):97*
• Knee injury, acute, assessing ligament stability, treatment and prevention. 76(8):38*
• Respiratory complications. 76(3):145
• Spinal deformities in children, diagnosis and treatment. 76(4):67*
• Upper extremity sports injuries, recognition and management. 76(4):45
• Wrist pain, causes and treatment. 76(5):117*

NASAL DISORDERS
• Allergic rhinitis, diagnosis, treatment. 76(1):197
• Manifestation of systemic disease. 76(3):100*

NECK
• Infections, life-threatening, early recognition and treatment. 76(8):69*

NEOPLASMS
• Adrenal gland, aldosterone-secreting, cause of hypertension. (CR) 76(2):173
• Association with nephrotic syndrome, incidence and clinical presentations, implications. 76(6):147*
• Bone, benign, in children. 76(4):89

continued

- Bone, malignant, in children. 76(4):92
- Breast, primary, management. 76(7):155*
- Cause of face pain. 76(2):141
- In acquired immune deficiency syndrome. 76(1):177
- Mediastinal, radiologic diagnosis. 76(3):173*

NERVES
- Cranial, appraisal of functions in evaluation of face pain. 76(2):167
- Trigeminal, association with face pain. 76(2):101*

NEUROLOGIC MANIFESTATIONS
- Amyotrophic lateral sclerosis or motor neuron disease, respiratory complications. (CR) 76(8):216
- Chronic disease, principles of providing compassionate care. 76(8):101*
- Evaluation with nuclear magnetic resonance imaging. 76(6):164
- Face pain: See Face
- Facial nerve paralysis, non-Bell's palsies, evaluation and management. 76(1):95*
- Headache: See Headache
- In spinal deformities, evaluation and treatment. 76(4):71
- Pain: See Pain
- Respiratory complications. 76(3): 143

NUCLEAR PHYSICS
- Laser therapy for eye disorders. 76(7):51*
- Nuclear magnetic resonance imaging, clinical applications. 76(6): 159*

NUTRITION
- Amino acid tryptophan for insomnia. 76(8):62
- Cholesterol, role in hyperlipidemia. 76(6):50
- Diet, in management of edema in nephrotic patients. 76(6):137
- Diet modification in treatment of hypertension. 76(5):65
- Folic acid, possible role in reducing cervical dysplasia. 76(8):63
- Magnesium supplementation, possible role in preventing coronary heart disease. 76(8):61
- Marine lipid hypothesis—fish oil capsules—to prevent cardiovascular disease. 76(8):62
- Rejection of unproven medical treatments in clinical nutrition, potential for erroneous rejection. 76(8):49
- Zinc deficiency in sickle cell disease, supplementation to stimulate growth. 76(5):249

OBSTETRICS/GYNECOLOGY
- Cervical condyloma, diagnosis and treatment. 76(6):42
- Cervical dysplasia, theory of reduction through folic acid supplementation. 76(8):63
- Pap smear screening, frequency and interpretation. 76(6):36*
- Pregnancy disorders, respiratory complications. 76(3):150
- Pregnancy, ectopic, diagnosis. 76(2):65*
- Pregnancy, effects of renal involvement. 76(6):125
- Pregnancy, high-risk, identification and monitoring. 76(4):35*
- Vaginal douching, pros, cons, and proper technique. (VP) 76(8):93
- Vulvovaginitis in adolescent girls, cause of dysuria, diagnosis and treatment. 76(8):207

OCCUPATIONAL DISEASES
- Asthma, causes and management. 76(5):179*

OCULAR DISORDERS: See Eye disorders

ONCOLOGIC DISEASES: See Neoplasms

OSTEOMYELITIS
- Hematogenous, diagnosis and treatment. 76(4):79*

OTORHINOLARYNGOLOGIC DISEASES
- Face pain, importance of ears, nose, and throat in evaluation. 76(2): 133*
- Face pain, neurologic causes. 76(2):161*
- Face pain, ocular causes. 76(2): 149*
- Face pain, overview. 76(2):90*
- Face pain, role of trigeminal nerve. 76(2):101*
- Face pain, temporomandibular joint disorders. 76(2):121*
- Neck infections, life-threatening, early recognition and treatment. 76(8):69*
- Vocal abnormalities, diagnosis and management. 76(4):25*

PAIN
- Chronic, pharmacologic and nonpharmacologic management. (VP) 76(2):215
- Face, association with trigeminal nerve. 76(2):101*
- Face, importance of ears, nose, and throat in evaluation. 76(2):133*
- Face, intracranial and extracranial sources. 76(2):161*
- Face, ocular causes. 76(2):149*
- Face, overview. 76(2):90*
- Face, temporomandibular joint disorders, dental evaluation. 76(2): 121*
- Wrist, causes and treatment. 76(5):117*

PARALYSIS
- Facial nerve, non-Bell's palsies. 76(1):95*
- Vocal fold, recognition and management. 76(4):31

PATIENT EDUCATION
- Drug administration instructions for elderly. 76(1):57
- For hearing impaired persons and their families. 76(3):195

PATIENTS
- Behavior during office visits. (PH) 76(7):18
- With chronic neurologic disease, behavior influencing care provided. 76(8):101

PEDIATRICS
- Adolescent girls, dysuria, evaluation with emphasis on nonurinary causes. 76(8):206*
- Bone tumors, diagnostic evaluation. 76(4):87*
- Gait problems, recognition and management. 76(4):56*
- Hip problems, early recognition. 76(4):97*
- Osteomyelitis, hematogenous, diagnosis and treatment. 76(4):79*
- Spinal deformities, diagnosis and treatment. 76(4):67*
- Sports participation, treatment and prevention heat-related disorders. 76(1):109*
- Student physicals, improved adequacy with five-minute examination. (OP) 76(4):106

PHYSICAL EXAMINATION
- Students, improved adequacy with five-minute examination. (OP) 76(4):106

PHYSICIAN-PATIENT RELATIONS
- Behaviors during office visits. (PH) 76(7):18
- Special considerations when patients have chronic neurologic disease. 76(8):101*

PHYSICIANS
- Acting on the basis of clinical impressions rather than scientific evidence. (ED) 76(8):13
- Anticipating patients' additional problems during office visits. (PH) 76(7):18
- Communications with attorneys. (PH) 76(3):30
- Criticism in press from colleagues, issue of free speech. (PH) 76(5):22
- Feelings about retirement. (OP) 76(2):81
- Hospital privileges, evaluating credentials. (ED) 76(4):9
- Humorous observations on profession. (PH) 76(1):22
- Medical records, importance of effective and timely completion. (OP) 76(8):219
- Medical training as preparation for public office. (ED) 76(5):13
- Observations on surgery. (PH) 76(2):22
- Practice personalized care or "generic medicine"? (PH) 76(8):22
- Providing compassionate care to patients with chronic neurologic disease. 76(8):101*
- Relations to other health professionals. (OP) 76(3):199
- Skipping out on disciplinary action. (ED) 76(2):13

PLASMIDS
- Epidemic, control through reduction in antibiotic use. 76(6):63*

PNEUMONIA
- Mycoplasmal, diagnosis and treatment. (CR) 76(6):71

POTASSIUM
- Hypokalemia and hypertension, caused by primary aldosteronism. (CR) 76(2):173

PREGNANCY: See Obstetrics/Gynecology

PREVENTIVE MEDICINE
- Glaucoma screening. (VP) 76(1): 224
- Immunizations for travel. 76(5): 243

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- Reducing impact of stress on disease incidence. (OP) 76(1):231
- Role of physician in promoting better health in patients. (OP) 76(5):223

PROSTHESIS
- Cochlear, to enhance communication skills of the deaf. 76(7):73*

PSYCHIATRIC/PSYCHOSOCIAL DISORDERS
- Functional or psychogenic illness, treatment by short-term group psychotherapy. 76(7):141*
- Insomnia, hypnotic treatment. 76(1):83*
- Mentally ill, deinstitutionalization, compassionate move or great mistake? (ED) 76(6):13
- Role of stress in disease. (OP) 76(1):231

PSYCHOTHERAPY, GROUP
- Short-term, for patients with functional or psychogenic illness. 76(7):141*

PUBLIC HEALTH
- Emergency medical care for mass gatherings, planning guidelines. 76(2):44*
- Preventable illnesses, role of physician in promoting better health. (OP) 76(5):223
- Sexually transmitted diseases among homosexual men—gay bowel syndrome—epidemiology, diagnosis, and treatment. 76(2):197

PULMONARY DISEASES: See Respiratory diseases

RADIOLOGIC DIAGNOSIS
- Arthrography, in acute knee injury. 76(8):43
- In temporomandibular joint disorders. 76(2):121
- Mammography to detect breast cancer. 76(7):159
- Mediastinal masses. 76(3):173*
- Nuclear magnetic resonance imaging, clinical applications. 76(6):159*
- Roentgenography, in acute knee injury. 76(8):42

REHABILITATION
- Following knee injury. 76(8):44

RENAL ARTERY
- Stenosis, cause of renovascular hypertension, treatment with balloon catheter angioplasty. 76(7):131

RESPIRATORY DISEASES
- Asthma and bronchitis, therapeutic inhalation agents and devices. 76(5):194*
- Asthma, diagnosis by bronchial provocation testing, guidelines for safe use. 76(5):161*
- Asthma, management. 76(1):209*
- Asthma, occupational, causes and management. 76(5):79*
- Asthma, role of arachidonic acid metabolites. 76(5):140*
- Dyspnea, manifestation of motor neuron disease or amyotrophic lateral sclerosis. (CR) 76(8):216
- Manifestations of systemic disease. 76(3):119*, 129*, 143*
- Mycoplasmal pneumonia, diagnosis and treatment. (CR) 76(6):71
- Pulmonary sarcoidosis, diagnosis and treatment. 76(3):168*
- Sinus pain, evaluation. 76(2):136

RESPIRATORY THERAPY
- Hyperbaric oxygen use, indications and risks. 76(5):83

RESUSCITATION
- Cardiopulmonary, community approach to improve survival rates. 76(3):86

RHEUMATIC DISEASES
- Impact on respiratory system. 76(3):119
- Laboratory testing in diagnosis and treatment. 76(3):155*

SCREENING
- For breast cancer. 76(7):155, 159
- For spinal deformities, evaluation and management. 76(4):67
- Pap smear, frequency and interpretation. 76(6):36*

SKIN DISEASES
- Atopic, characteristics. 76(1):118
- Atopic dermatitis, recognition, treatment. 76(1):139*
- Leg ulcers, recognizing underlying disorder. 76(4):51*
- Respiratory complications. 76(3):145
- Urticaria and angioedema, diagnosis, treatment. 76(1):183*

SLEEP DISORDERS
- Hypnotic treatment. 76(1):83*
- Insomnia, treatment with amino acid tryptophan. 76(8):62

SMOKING
- Cessation, role of physician. (OP) 76(5):223

SOCIAL RESPONSIBILITY
- Deinstitutionalization of mentally ill, compassionate move or great mistake? (ED) 76(6):13

SPINAL DISEASES
- Evaluation, management. 76(4):67*

SPORTS MEDICINE
- Heat-related disorders associated with exercise, treatment and prevention. 76(1):109*
- Injuries to upper extremity, recognition and management. 76(4):45

STRESS
- Effect on disease incidence. (OP) 76(1):231

SURGERY
- Breast, changes in procedures over the years. 76(7):155, 159
- Esophageal, Hill procedure with intraoperative manometry for esophageal reflux. 76(7):77*
- Hand, in treating causes of wrist pain. 76(5):117
- Laparotomy for ectopic pregnancy. 76(2):68
- Observations. (PH) 76(2):22
- Plastic, to treat changes in face brought on by aging. 76(7):44

SYSTEMIC DISEASES: See also individual diseases and systems
- Nasal manifestations, recognition and treatment. 76(3):100*
- Respiratory manifestations. 76(3):119*, 129*, 143*
- Sarcoidosis, diagnosis and treatment. 76(3):167*

TECHNOLOGY, MEDICAL
- Computer security techniques. 76(6):171
- Computer security techniques for physician's office. 76(8):187
- Image processing in health care. 76(2):73
- Intraoperative manometry, use during antireflux surgery. 76(7):79
- Microcomputers in medical practice. 76(1):239
- Nuclear magnetic resonance imaging, clinical applications. 76(6):159*

THERAPEUTICS
- Angioplasty, balloon catheter, in treatment of renovascular hypertension. 76(7):131*
- Collagen implant to treat aging facial skin. 76(7):44
- Cryoprecipitate, for coagulation factor disorders. 76(8):122
- Dermabrasion and chemabrasion to treat aging facial skin. 76(7):43
- Food injection for food allergy, review. 76(2):59
- Group psychotherapy, short-term, for patients with functional illness. 76(7):141*
- Hyperbaric oxygen use, indications, risks. 76(5):83*
- Inhalation agents and devices for asthma and bronchitis. 76(5):194*
- Insulin infusion pumps, principles of use. 76(8):80*
- Laser photocoagulation therapy for eye disorders. 76(7):51*
- Nonpharmacologic management of chronic pain. (VP) 76(2):216
- Phlebotomy, for polycythemia vera. (VP) 76(5):98
- Rejection of unproven medical treatments in clinical nutrition, potential for erroneous rejection. 76(8):49
- Transfusion, granulocyte, for granulocytopenia. 76(8):179
- Transfusion, platelet, for thrombocytopenia. 76(8):175

THORAX
- Evaluation with nuclear magnetic resonance imaging. 76(6):165
- Mediastinal masses, radiologic diagnosis. 76(3):173*

TRAUMA
- In hematogenous osteomyelitis. 76(4):79, 80
- To upper extremity, caused by sports activities, management. 76(4):45*

TRAVEL MEDICINE
- Immunization recommendations. 76(5):243

TUMORS: See Neoplasms

ULCER
- Leg, recognizing underlying disorder. 76(4):51*

URINARY TRACT DISORDERS
- Dysuria in adolescent girls, evaluation with emphasis on nonurinary causes. 76(8):206

URINE TESTING
- In diabetes management, study of double-void technique. (VP) 76(3):204

VASCULAR DISEASES: See Cardiovascular diseases

VENEREAL DISEASES
- Gay bowel syndrome, diagnosis and treatment. 76(2):197*

VENOUS INSUFFICIENCY
- Cause of leg ulcers, treatment. 76(4):51

VIRAL DISEASES
- Acquired immune deficiency syndrome, causes and therapy. 76(1):167

VOICE DISORDERS
- Diagnosis, treatment. 76(4):25*

WARFARIN
- Use as oral anticoagulant for thrombotic disorders, pharmacology, dosing, adverse effects, and clinical uses. 76(8):158

WOUNDS/INJURIES: See Trauma

ZINC
- Deficiency in sickle cell disease, supplementation to stimulate growth. 76(5):249

AUTHORS

AAGAARD GN
Management of hypertension in the elderly: The case for 'hygienic' measures over drug therapy. 76(5):61

ADLER J
Diagnosis of dysuria in adolescent girls: A protocol encompassing common, often nonurinary, causes. 76(8):206

ALMOG C
See Burke M

ANSARI A
Mallory-Weiss syndrome: Experience in a community hospital. 76(8):189

BACHMAN JW
Cardiac arrest in the community: How to improve survival rates. 76(3):85

BALDWIN JG Jr
Erythrocytosis: A guide for rapid evaluation. (VP) 76(5):98

BALLOW M
Allergic rhinitis and conjunctivitis: Help for the weeping nose and eyes. 76(1):197

BARKER JM
A primary care MD's report on the American College of Cardiology Annual Session. 76(2):231

BARNES NC
Mast-cell-derived mediators in asthma: Arachidonic acid metabolites. 76(5):140

BATSON E
Computer security. 1. Protecting data from prying eyes. 76(6):171
Computer security. 2. Three methods for the physician's office. 76(8):187
Image processing: Where computers have had greatest medical impact. 76(2):73
Kids and computers: Does your child really need one? 76(5):237

continued

BECK HJ
Life-threatening neck infections: Early diagnosis to forestall crisis. 76(8):69
BEYER CB
Heat stress and the young athlete: Recognizing and reducing the risks. 76(1):109
BURKE SI
'Essential' hypertension with hypokalemia caused by aldosterone-secreting adrenal adenoma. (CR) 76(2):173
BURNETT LL
See Bush WH
BUSH WH
Balloon catheter angioplasty: Which patients with renovascular hypertension are candidates? 76(7):131

CARAVEO J
See Holguin M
CARO I
See Larrabee WF Jr
CLARK JL
Introduction to symposium on face pain. 76(2):88
An overview of face pain. 76(2):90
CONNOLLY SSJ
Occupational asthma: Update on a proliferating problem. 76(5):179
CONRAD KA
Innovations in drug delivery. 76(5):71
COONEY WP III
Sports injuries to the upper extremity: How to recognize and deal with some common problems. 76(4):45
COSTELLO JF
See Barnes NC
CROSS CE
Introduction to symposium on hyperreactive airway diseases. 76(5):136

DAUL CB
Acquired immune deficiency syndrome (AIDS): Medical challenge of the 80s. 76(1):167
DAVIS JM
The 'Oh, by the way, Doctor' syndrome. (PH) 76(7):18
DeREMEE RA
Sarcoidosis: Current perspectives on diagnosis and treatment. 76(3):167
deSHAZO RD
Introduction to symposium on allergy/immunology. 76(1):116
See also Daul CB
DeWITT DE
Immunization: A shot in the arm for travelers. 76(5):243
DOE RP
See Kaiser FE
DONFMAN SF
Ectopic pregnancy: 'Thinking ectopic,' key to diagnosis. 76(2):65
DOUGHERTY RJ
Office management of chronic pain. (VP) 76(2):215
DOZIER RE
Take a look over the fence at the rest of the medical world. (OP) 76(3):199
DUANE DD
Neurologic analysis of face pain. 76(2):161

FARRAR CL
The cochlear prosthesis: Bringing the world of sound to the deaf. 76(7):73

FEINSTEIN RJ
Skipping out: A game no one wins. (ED) 76(2):13
FENSTER LF
Reactive hepatopathy: Liver signs without primary liver disease. 76(7):62
FIELD CS
High-risk pregnancy: Identification and monitoring to improve outcome. 76(4):35
FOSTER RJ
Wrist pain: How to identify the cause and treat it. 76(5):117
FRYER DG
Seattle's past and present shape the Mason Clinic's future. (ED) 76(7):13

GEBHARDT MC
Bone tumors in children: Differential characteristics and treatment. 76(4):87
GIBILISCO JA
Dental perspective on face pain. 76(2):121
GILLETTE RD
Medical records: Friend or foe? 76(8):219
GLATTER TR
Hyperlipidemia: What is 'normal,' who should be treated and how. 76(6):49
GODDEN D
See Higenbottam T
GREEN JB III
Hereditary and acquired coagulation factor abnormalities: A primary care primer. 76(8):118
GROSS JA
See Malcolm R
GROSS RH
Hip problems in children: Aids to early recognition. 76(4):97
Introduction to symposium on musculoskeletal disorders in children. 76(4):55

HARRELL LE
See Massey EW
HARRIS LF
Mycoplasmal pneumonia: Three severe cases of a common infection. 76(6):71
HEGSTROM RH
See Orme BM
HENDRICK DJ
See Connolly MJ
HERNDON WA
Spinal deformities in children: The improving picture. 76(4):67
HIGENBOTTAM T
Inhalation challenge testing for asthma: Role of bronchial provocation testing in clinical practice. 76(5):161
HILL LD
See Mercer CD
HOLGUIN M
Thrombocytopenia and granulocytopenia: Characteristics, causes, evaluation, and management. 76(8):171
HORWITZ DL
Insulin pump therapy: Rationale and principles of use. 76(8):80
HORWITZ LD
Congestive heart failure: An overview of drug therapy. 76(2):187
HOUSTON TP
Priorities in health promotion: Combating the epidemic of preventable illness. (OP) 76(5):223

HOWARD RB
All pathologists eat lunch early: Thoughts on unfounded generalizations. (ED) 76(8):13
DRGs: Prospective payment/prospective horror. (ED) 76(1):13
Hospital privileges: Yet another battleground. (ED) 76(4):9

KAISER FE
Steroid use in the elderly: Guidelines for avoiding adverse effects. 76(1):65
KASSER JR
Hematogenous osteomyelitis: Untangling the diagnostic confusion. 76(4):79
KAUFMAN CE
Fluid and electrolyte abnormalities in nephrotic syndrome: Pathogenesis and management. 76(6):135
KLEIN R
Little 'hospital' on the prairie: Roughly the first hundred years of Rochester's Mayo Clinic. (ED) 76(3):15
KOLLARITS CR
The eye and face pain. 76(2):149
KUPRENAS SV
See Farrar CL

LAMY PP
Hazards of drug use in the elderly: Commonsense measures to reduce them. 76(1):50
LARRABEE WF Jr
The aging face: Why changes occur, how to correct them. 76(7):37
LEVINSON AI
Urticaria and angioedema: Current approach to common problems. 76(1):183
LINDEMAN RC
The Mason Clinic: Its special role in the Pacific Northwest. (ED) 76(7):11
LLACH F
Introduction to symposium on nephrotic syndrome. 76(6):87
Thromboembolic complications in nephrotic syndrome: Coagulation abnormalities, renal vein thrombosis, and other conditions. 76(6):111
LOFGREN EP
Leg ulcers: Symptom of an underlying disorder. 76(4):51

McCAFFREY TV
See Beck HJ
McCARTHY J
Value of urine glucose tests in management of type II diabetes mellitus: Results of a study of the double-void technique. (VP) 76(3):204
McDONALD TJ
Introduction to symposium on airway in systemic disease. 76(3):99
Nasal manifestations of systemic disease. 76(3):100
McGOON MD
See Vlietstra RE
MALCOLM R
Insomnia and its treatment: When are hypnotics justified? 76(1):83
MALDEN M
Chronic neurologic disease: Easing the special problems of long-term care. 76(8):101
MANDELL HH
Attorneys and physicians. (PH) 76(3):30
The dawn of generic medicine. (PH) 76(8):22

École d'anthropologie. (PH) 76(1):22
Freedom of the press: Tale of a physician-iconoclast. (PH) 76(5):22
A modern Norse (odontologic) saga. (PH) 76(6):22
The nonsurgical death syndrome. (PH) 76(2):22
MANGHAM CA Jr
See Farrar CL
MARAGOS NE
Vocal abnormalities: What listening can tell you. 76(4):25
MASSEY EW
Motor neuron disease presenting with respiratory failure: Report of two cases. (CR) 76(8):216
MAYBERRY WE
The Mayo Clinic in 1984: Preserving the founding values amidst modern diversification. (ED) 76(3):13
MELSON SJ
See Rynearson EK
MENSHER JH
Laser therapy for eye disorders. 76(7):51
MERCER CD
Gastroesophageal reflux disease: What to do when conservative measures fail. 76(7):77
MILLIKAN LE
Atopic dermatitis: Clinical spectrum and approach to treatment. 76(1):139
MITAS JA II
Nephrotic syndrome: Pathogenesis, clinical and therapeutic considerations. 76(6):88
MUHM JR
See Parish JM
MYERS RA
Hyperbaric oxygen use: Update 1984. 76(5):83;(correction) 76(8):32

NELSON HS
What is atopy? Sidestepping semantics. 76(1):118
NEMEC LA
See Zbella EA
NEWMAN SP
Therapeutic inhalation agents and devices: Effectiveness in asthma and bronchitis. 76(5):194

OLSEN KD
Facial nerve paralysis. 2. 'All that palsies is not Bell's.' 76(1):95
OLSEN WO
Presbycusis: When hearing wanes, is amplification the answer? 76(3):189
ONROT J
Hypertension in the elderly: The benefits of therapy. 76(5):46
ORME BM
Drugs for hypertension: Seven classes to choose from. 76(7):84
Economics of antihypertensive therapy. 76(7):97
Introduction to symposium on hypertension. 76(7):83
OSTERGAARD D
See DeWitt DE

PALMER RL
Laboratory diagnosis of bleeding disorders: Basic screening tests. 76(8):137
PANSKY B
Neuroanatomic basis of face pain: The fifth (trigeminal) nerve. 76(2):101

PAPO J
See Burke M
PAPPER S
Nephrotic syndrome and neoplasm: The findings to date, with practical implications. 76(6):147
PARIS PM
See Whipkey RR
PARISH JM
Mediastinal masses: Clues to interpretation of radiologic studies. 76(3):173
PATON RR
Adjusting the hypertension regimen: Simple method based on circulatory assessment. 76(7):115
PAULL BR
Imported fire ant allergy: Perspectives on diagnosis and treatment. 76(1):155
PEARSON BW
ENT approach to face pain. 76(2):133
PERRY WJ
A physician's prologue to retirement. (OP) 76(2):81
PODELL RN
Food extract injection for food sensitivity: Valid technique or 'black magic'? 76(2):59
The 'tomato effect' in clinical nutrition: New treatments languishing on the vine? 76(8):49
Zinc supplementation: Evidence of growth stimulation in sickle cell disease. 76(5):249
PRAKASH UB
Respiratory manifestations of systemic disease. 1. Rheumatologic and vascular diseases. 76(3):119
Respiratory manifestations of systemic disease. 2. Hematologic, endocrine and metabolic, renal, and gastrointestinal diseases. 76(3):129
Respiratory manifestations of systemic disease. 3. Neurologic, skeletal, dermatologic, gynecologic, and gonadal diseases and disorders of pregnancy. 76(3):143

QUICK D
Use of anticoagulants: Therapy and prophylaxis for thromboembolic phenomena. 76(8):151
QUINN TC
Gay bowel syndrome: The broadened spectrum of nongenital infection. 76(2):197

RANKIN LI
Nephrotic syndrome and pregnancy: Potential problems for mother and child. 76(6):125
RIORDAN ML
Medicine: An apt preparation for public office. (ED) 76(5):13
RODMAN WP
Glaucoma screening by the primary care physician. (VP) 76(1):224
ROSENOW EC III
See Parish JM
RUDOLPH RH
Management of primary breast cancer: What the past decade has taught us. 76(7):155
RYNEARSON EK
Short-term group psychotherapy: A successful approach to functional complaints. 76(7):141

SCHNITZER BM
See Myers RA
SCOTT JH
The one-minute physical versus the five-minute physical: And the winner is . . . . (OP) 76(4):106
SHUB C
Angina pectoris: Clinical strategies in diagnosis. 76(3):50
SINATRA ST
Stress: A cardiologist's point of view. (OP) 76(1):231
SMITH L
See Summers R
STAVOROVSKY M
See Burke M
STEWART RD
See Whipkey RR
SUMMERS R
Asthma management: New perspectives, improved options. 76(1):209
SWANN P
See Harris LF

TROWBRIDGE AA
Introduction to symposium on bleeding disorders. 76(8):117
See also Quick D

VANNIER MW
Nuclear magnetic resonance imaging: The case for prudent use in clinical diagnosis. 76(6):159
VERMESH M
See Zbella EA
VLIETSTRA RE
Beta-adrenergic blockers: Choosing among them. 76(3):71
VOLLERTSEN RS
The laboratory in rheumatology: A guide for clinicians. 76(3):155

WASSERSUG JD
Mental health hits the gutter: The sad outcome of a 'noble' experiment. (ED) 76(6):13
WELCH HG
Antibiotic resistance: A new kind of epidemic. 76(6):63
WHIPKEY RR
Emergency care for mass gatherings: Proper planning to improve outcome. 76(2):44
WILBURN RL
Mild hypertension: Should all patients be treated? 76(7):107
WOOD AJ
See Onrot J
WRÓBLEWSKI F
Office laboratory equipment: Should you consider automation? 76(5):211

YEOH JW
The many uses of microcomputers. 76(1):239
YNGVE DA
Gait problems in children: A matter of rotation. 76(4):56

ZBELLA EA
Vaginal douching: Pros, cons, and proper technique. (VP) 76(8):93
ZEMAN SC
Acute knee injury: How to determine if the knee is stable. 76(8):38
ZUNA RE
The Pap smear revisited: Controversies and recent developments. 76(6):36

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